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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,794	06/25/2003	Syed F.A. Hossainy	50623.221	3469

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EXAMINER	
SELLMAN, CACHET I	
ART UNIT	PAPER NUMBER
1792	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,794	HOSSAINY ET AL.	
	Examiner	Art Unit	
	CACHET I. SELLMAN	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) *36-58 and 64-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-29,31-35,59-62 and 75-82* is/are rejected.

7)☐ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/2/2005;10/01/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 36-58 and 64-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/ species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/30/2008.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/108,004 and 10/304,360, and 09/750,595, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In the instant application, claims 1, 21, 60 and 76-77 include new subject matter of forming a "dry coating" having "less than

about 2% residual fluid content (w/w)" which is not disclosed in the specification of the parent applications 10/108,004 and 10/304,360, and 09/750,595. Therefore the earliest priority date for the new subject matter claims 91-12, 21-22, 60 and 76-77) is June 25, 2003.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 13-15, 17-24, 28-29, 75 -76, and 78-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy et al. (US 6153252).

Hossainy et al. discloses a process for applying a coating to a stent. The process comprises applying a composition having a polymer and a solvent (see col. 4,line 1 – col. 6, line 67); allowing the solvent to evaporate (see Example 1). The polymer applied in Example 1 is a copolymer of 45:55 e-caprolactone and glycolide which has a glass transition temperature of -8 C and a melting point temperature of 65^{o}C as evidence, see US patent 5,468,253 (examples 3-5) which was determined using DSC. The composition after being applied to the stent is air dried for 12 hours followed by heating in a 60^{o}C vacuum oven for 24 hours. As shown the stent is heated to a temperature which is greater than the glass transition temperature as required by **claims 13 and 75**.

The composition may or may not include an active agent (see col. 10, line 24-25) as required by **claims 14 and 79-80**. A primer layer is formed prior to applying the coating composition (see Example 1) as required by **claim 15**. A top coat can be applied in order to delay release of the agent (see col. 7, line 18-20) as required by **claim 17**. The active agent can be rapamycin (see col. 8 ,line 31) which does not degrade at the heating temperature as required by **claims 18, 20 and 81**. The drying is a rapid process so as to not diffuse the drug into the coating (see col. 9,lines 18-20) as required by **claim 19.**The coating is completely dried as required by **claims 21-22 and 76**. The temperature that the coating is heated to in lower than the melting temperature of the polymer as required by **claim 23**. The composition may include one or more additives, e.g., nontoxic auxiliary substances such as diluents, carriers, excipients, stabilizers or the like. It is noted by the Examiner that any additive to the polymer composition inherently changes the thermal energy profile of the polymers such as Tg or Tm, absent any clear and convincing evidence and/or arguments to the contrary as required by **claim 24**. As stated above, the glass transition temperature was determined using differential scanning calorimetry as required by **claim 28**. The polymer is a copolymer meaning it is a blend of two or more polymers as required by **claim 29**. The device is a metallic stent and the coating is applied to the metallic portion (see col. 3, lines 12-14) as required by **claim 78**.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-7, 11-12, 16, 26-27, 31-35, 59-62 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6153252).

Hossainy et al. discloses a process for applying a coating to a stent. The process comprises applying a composition having a polymer and a solvent (see col. 4,line 1 – col. 6, line 67); allowing the solvent to evaporate (see Example 1). The polymer applied in Example 1 is a copolymer of 45:55 e-caprolactone and glycolide which has a glass transition temperature of -8 C and a melting point temperature of 65°C as evidence, see US patent 5,468,253 (examples 3-5) which was determined using DSC. The composition after being applied to the stent is air dried for 12 hours followed by heating in a 60°C vacuum oven for 24 hours.

Hossainy et al. does not explicitly teach that a dry coating having less than about 2% residual fluid content is heated to a temperature greater than ambient temperature for a duration of time. However, Hossainy et al. does teach heating the composition on the stent until it is completely dry therefore it would have been obvious that at some point in the drying period the coating reached a point where it comprised less than 2 % residual fluid and was continually heated until it was completely dry having no residual fluid therefore the limitations of **claims 1, 11 and 77** are met. As shown in example 1, a primer layer is applied to the stent followed by a reservoir layer having the active agent as required by **claim 2**.

Hossiany et al. teaches a top coat can be applied to prevent release of the active agent (see col. 7, line 18-20) as required by **claim 3**. The device is a stent as required by **claim 4**. The active agent does not degrade when exposed to the temperature as required by **claim 6**. The drying is a rapid process so as to not diffuse the drug into the coating (see col. 9, lines 18-20) as required by **claim 7**. The active agent can be rapamycin (see col. 8, line 31) as required by **claim 12**.

In regards to **claim 16**,

The top coat can be formed of the same or different polymer but with a different solvent therefore when it is heated the solvent in the barrier layer would evaporate prior to the solvent of the coating. One would have applied the barrier coating prior to exposing the coating to a temperature higher than glass transition to get the same effect as if the layer was formed after heating the coating.

Hossiany teaches that polymer used can be aliphatic polyesters, polyamides and homopolymers and copolymers of lactide, such as d-, l-, lactic acid and mesolactide. It is noted by the Examiner that the copolymer of d-, l-lactic acid is an amorphous polymer as required by **claim 31**.

In regards to **claims 32-33**,

Hossainy teach that a suitable polymer includes polyamides of the form -NH-(CH2)x-NH-CO-(CH2)y-CO-, wherein x is an integer in the range of 6-12 and y is an integer in the range of 4-16, i.e., a block or graft copolymer.

In regards to **claims 26-27 and 34 and 35**,

Hossainy does not teach heating a polymer that exhibits two or more Tg to a temperature equal to or greater than the lowest or highest exhibited glass

transition temperatures in that polymer. However, it would have been obvious to one having ordinary skill in the art to heat the polymer to a temperature that is above the lower or highest glass transition temperature through routine experimentation in order to ensure that the coating is adequately adhered therefore the temperature is a result effective variable because it determines how well the polymer adheres to the stent. Also, Hossainy et al. teaches that the polymers must adhere to the stent and not be so readily deformable after depsotioin to the stent as to be able to be displaced by hemodynamic stresses. Additionally it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See M.P.E.P 2144.05 II B.

In regards to claim 59,

It is well known in the art that by heating the coating especially since the temperature is above the glass transition temperature the crystallinity will increase. The limitations of **claims 60-62** were addressed above.

7. Claims 1, 8, 11, 13, 25, 75, 77 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 645137).

Hossiany et al. teaches a process for applying a composition having a therapeutic substance, a fluid and a polymer to a prosthesis and removing the fluid (see abstract, col. 5, line 49). The polymer can be bioabsorbable polymers such as poly-D, L-lactic acid, polycaprolactone, etc or biostable polymers such as polyethylene vinyl acetate, ethylene vinyl alcohol copolymers (see col. 5, line 49 - col. 6, line 13 and Examples). The fluid/solvent is removed by exposing to heat at 60 - 65^{o}C under vacuum conditions.

Hossainy et al. does not explicitly teach that a dry coating having less than about 2% residual fluid content is heated to a temperature greater than ambient temperature for a duration of time. However, Hossainy et al. does teach heating the composition on the stent until it is completely dry therefore it would have been obvious that at some point in the drying period the coating reached a point where it comprised less than 2 % residual fluid and was continually heated until it was completely dry having no residual fluid therefore the limitations of **claims 1, 11, 75 and 77** are met. The polymer can be ethylene vinyl alcohol copolymer, ethylene vinyl acetate copolymer as required by **claims 8 and 82**.

In regards to **claim 13**, the polymer can be ethylene vinyl acetate copolymer which when heated to 60-65oC is greater than the glass transition temperature therefore meeting claims 13 and **25**.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or

patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 10, 11, 13-14, 21-24, 26-27, 29, 31-35, 59, and 75-80 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 12-17, 33, 62, and 80 of copending Application No. 10/856,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 of '984 is directed to coating an implantable device with a composition forming a dry coating having 0% of solvent then heating the coating to a temperature equal to or greater than the glass transition temperature. Claim 1 is a narrower claim than claim 1 of the pending application therefore it anticipates the claim as well as claims 13 and 75 of the current pending application.

10. Claims 10, 11, 14, 21-24, 26-27, 29, and 31-35 of the current application are anticipated by claims 2, 4-6, 12, 13-17, and 80 of application '984.

11. Claim 33 of '984 teaches applying a composition to a stent having a solvent and polymer; allowing the solvent to evaporate; and exposing to a temperature sufficient to increase the crystallinity of the polymer by 5 to 30%. Claim 33 is a narrower claim than claim 59 of the current application therefore it anticipates the claim.

12. Claims 78-80 are anticipated by claims 4-6 of application '984.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CACHET I. SELLMAN whose telephone number is (571)272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1792

/C. I. S./
Examiner, Art Unit 1792

/William Phillip Fletcher III/
for Timothy H. Meeks, SPE of Art Unit 1792/1700